# MEDIPHACOS EE EMB 14 - Keraring Review 09 Page 1of 10 Elaboration: Karine Lima Review: Ana Luiza Duz Approval: Cláudia Azevedo Date: October 28, 2022

# I. REASON FOR REVIEW

Review	Historic	Approval Date
09	Review of the specifications of packaging materials in compliance with the actions by the selected materials Gap Analysis GA01/2021, 14/2021, 15/2021, 19/2021, 09/2022 and 34/2022 and by the Change Controls CM 17/2021, 18/2021, 25/2021, 02/2022 and 05/2022.  According to the proposed amendments ID 11/2022.  There is no training that requires an implementation of the document in the QMS.	October 24, 2022
00	Initial issue.	January 8, 2019

## **GOAL**

Provide the specifications of the packaging and labeling used in the models of the Keraring Intrastromal Corneal Ring product (SI5, SI6, SG, AS5 and AS6) under the scope of the CE marking.

# II. SCOPE

This document applies to the Production (Implant Quality and Cleaning - QLI and Packaging), Supply, Logistics and Quality Management and Regulatory Affairs sectors.

# III. TECHNICAL SPECIFICATIONS

# 4.1. Models and Specifications

## 4.1.1 Primary packaging

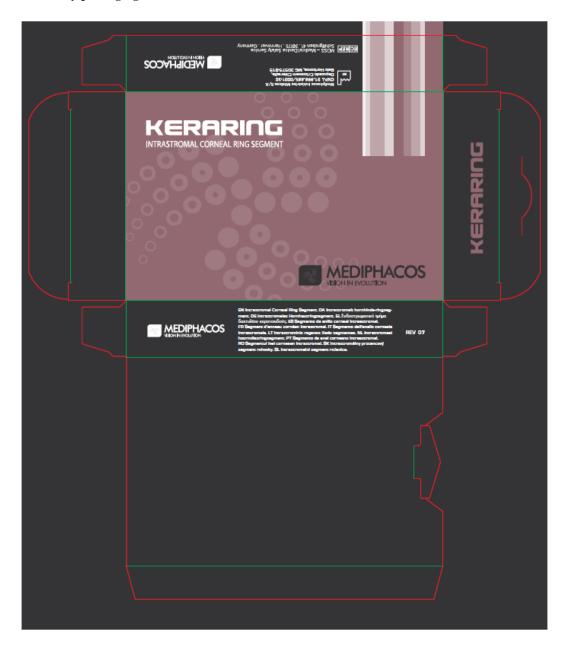
See current version DET IC 14.

# 4.1.2. Secondary packaging

See current version DET IC 30.

EE EMB 14 - Keraring Review 09 Page 2 of 10

# 4.1.3 Tertiary packaging:



• Layout: 200020004 Keraring Cardridge Rev 07

• **Dimensions (close):** 96 x 26 x 145 mm

• **Dimensions (open):** 25,5 x 24,0 cm

• Material: black ink in lamination and gloss on side 1

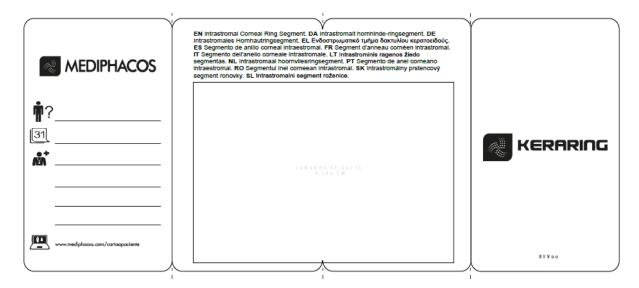
Grammage: 325 gCollors: 3 x 0

• Pantones: 8062 C, 7633 C and Black C

EE EMB 14 - Keraring Review 09 Page 3 of 10

## 4.1.4 Implant card:

## **FRONT**



## VERSE

EN Instruction for completion. DA Instruktion til færdiggørelse. DE Anleitung zum Austillen. EL Oбnyke; vva ougnikljoson. ES Instructiones para completer. FR Instruction pour l'achèvement. III Istruzioni per il completamento. LI Uzpidrymo instrukcija. NL Instructie voor voltooling. PI Instruzio para conclusão. RO Instructiune pentru completare. SK Polyon na dokončenie. SL Navodilo za dokončanje.

EN To be filled by the healthcare institution/provider. DA Udrijdes af sundhedsinstitution/udrijder. DE Von der Gesundheitseinrichtungidem Leistungserbringer auszufüllen. EL Συμπληρώνεται από το ίδρομα / πάροχο υγείος, ES Para ser lienado por la institution/proveedor de salud. FR Aremplir par l'établissementiprestataire de soins. IT Da compliare a cura dell'entelprestatore sanitário. LP Pildo svelkatos įstalga. cura deri emerprestatore santano. Li prou severatos statiga-paslaugu telielisa. NL In te vullen door de zorginstellingaan-bieder. PT A ser preenchido pela instituição/prestador de saúde. RO A se completa de catre instituicia/punizorul de santates. SK Wyhlin izdravorhá instituicia/poskytovate! SL Izpoini zdravistveni zavod/tzvajelec:

WY

EN Patient Name or patient ID. DA Patientens navn. DE
Patientenname. EL Övoμα ασθενούς. ES Nombre del
paciente. FR Nom du patient. IT Nome del paciente. L'
Paciento vardas ir pavarde. NL Naam patient Pasientens
navn. PT Nome do doente. RO Nume pacient. SK Meno
pacients SI (Im po Jonika.)

ES.

EL Date of Implantation. DA Implementeringsdato. DE
Umsetzungsdatum. EL Ημερομηνία εμφότευσης. ES
Fecha de implantación. FR Date d'implantation. IT Data
dell'implanto. LT Implantavimo data. NL Implementatiedatum. PT Data do implante. RO Data implantàrii. SK
Dátum implantácie. SL Datum implantacije

EN Name and Address of the implanting healthcare institution/provider. DA Navn og adresse på den implanterende sundhedsinstitution/udbyder. DE Name und Adresse der implantierenden Gesundheitseinrich-tung/des, Anbieters. EL Όνομα και διεύθυνση του εμφιτευόμενου δρομιατοζηπορίχου "υγειονόμικης περίθαλψης, ES Nombre y dirección de la institución/proveedor de salud que implanta. FR Nom et adresse de l'établissement de santé/prestataire d'implantation. IT Nome e indirizzo dell'istituto/operatore sanitario che effettua l'impianto. LT Implantuojančios sveikatos Priežiūros įstaigos/teikėjo pavadinimas ir adresas. NL Naam en adres van de implanterende zoginstelling/aan-bieder. PT Nome e endereço da instituição/provedor de saúde implantado. RO Numele și adresa instituţiei/fumizorului de asistentă medicală care implantează. SK Názov a adresa implantujúceho zdravotníckeho zariadenia/poskytovateľa. SL Ime in naslov zdravstvene ustanove/izvaja/ca implantacije

MD EN Device Name. DA Enhedsnavn. DE Gerätename. EL Ovoju της συσκευής. ES Nombre del dispositivo. ER Nom de Tapparell. IT Nome del dispositivo. IT Irenginio pavadnimas. NI Toestelnam. PT Nome do dispositivo. RO Nume dispositiv. SK Názov zariadenia. SL Ime

EN Manufacturer. DA Fabrikant. DE Hersteller. EL Kortooksvoortif, ES Fabricante. FR Fabricant. IT Produttore. LT Gamintojas. NL Fabrikant. PT Fabricante. RO Producător. SK Výrobca. SL Proizvajalec

EN Information 

EN Serial number. DA Serienummer. DE Serie EN Seria number. De Serienminner. De Serienminner. EL σειριακός αμθμός. ES Número de serie. FR Numéro de série. IT Número di serie. LT Serijos numeris. NL Serienummer. PT Número de série. RO Număr de serie. SK Sériové číslo. SL Serijska številka DT EN LOT number. DA Partinummer. DE Chargennummer. EL αριθμός παρτίδος, ES Numero de lote. FR Numéro de lot. IT numero di lotto. LT Partijos numeris. NL Lotnummer. PT Número de lote. RO Numărul lotului. SK číslo parcely. SL številka serije

EN Unique Device Identifier, DA Unik, enheds-id. DE Endeutige Gerätekennung. El Movobixo avayvuopiotuko ovoevojc. ES Identificador unico de dispositivo. FR Identificator unique de Tapanerell. TI Identificator dispositivo univoco. LT Unikalus irenginio Identifikator dispositivo exclusivo. RO Identificator unic de dispositivo exclusivo exclusivo avaitator arriadore indentifikator raprave UDI-DI -

UDI-DI

RI Unique numeric code specific to a device model. DA Unik
numerisk lode specifik for en enhedsmodel. DE Eindeutiger
numerischer Code, der für ein Gerätemodel spezifisch ist. Ek
Movoßwöc queldprünöc wöböröc volwespülzero vol ein
portabo otwischer. El Codigo numeriro unique especific
para un modelo de dispositibis. PE Code numerirou unique
specifique à un modele d'appareil. IT Codice numeriro
univoco specifico per un modelo di dispositivo. II Unikalus
skattmennis kodas. biudingas jrenginio modeliut. NI. Uniele
numeriele code die specificik si vol'eren apparaatmodel PT
Codigo numeric vecturalvio especific para un modelo de
dispositivo. RO Cod numeric unic specific unui model de
dispositivo. Re beninchy disently kod specificky pre model
zariadenia. SI Edinstvena stevifica koda. znacilina za model
zaparave.

Layout: 200050081 Keraring Implant Card Rev00

**Dimensions:** 320 x 95 mm

Material: black ink on vitabianco card, gloss lamination

Weight: 325 g (printed double-sided with creases for 03 folds)

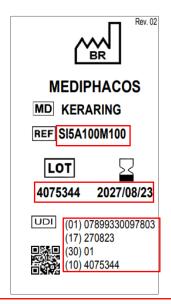
Pantone: Black C

**Disposition**: inserted inside the tertiary packaging (cartridge)

EE EMB 14 - Keraring Review 09 Page 4 of 10

## **4.1.5** Labels

## 4.1.5.1 Primay packaging label



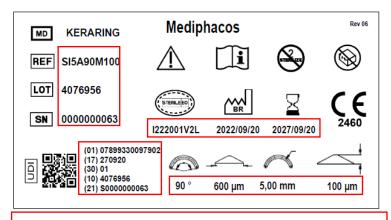
Variable data: reference, lot (OP), expiration date and UDI

• Layout: 200050026 Universal Case Label Rev 02

Dimensions: 44 x 22 mmMaterial: couchê borracha

• **Disposition:** affixed in the primary packaging (case) of the product.

# 4.1.5.2 Secondary packaging label



**Variable data:** reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

Layout: 200050003 Zebra Autofit Tag Rev 06

• **Dimensions:** 97 x 220 mm

Material: resin adhesive, transthermic
Front material: 67 to 75; 71 micron
Protective material: 52 to 59; 55.5 g/m2
Total weight: 133 to 150; 141.5 g/m2
Total thickness: 132 to 150; 141 micron

Release: 6 to 14; 180° gf/1inType of printing: flexography

• Varnish: no

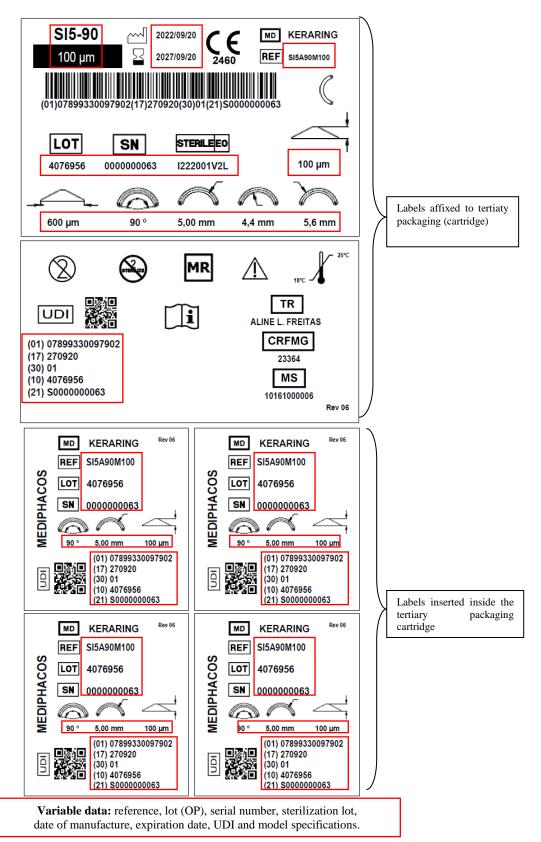
• **Minimum spacing:** 3mm ±1

EE EMB 14 - Keraring Review 09 Page 5 of 10

• Disposition: affixed in the secondary packaging (envelope) of the product.

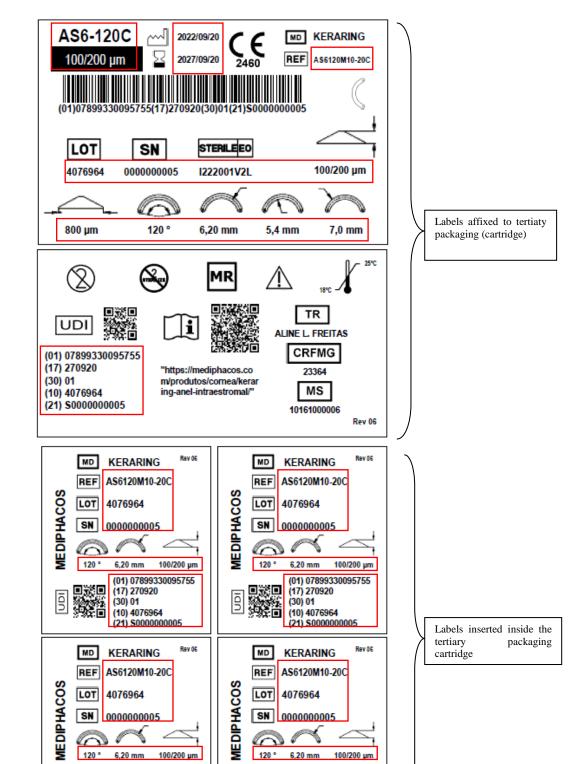
## 4.1.5.3 Tertiary packaging labels:

a) Symmetric models: SI5 and SI6



EE EMB 14 - Keraring Review 09 Page 6 of 10

## b) Asymmetric models: ASI5 and ASI6



(01) 07899330095755

(17) 270920

(10) 4076964

(21) \$0000000005

(30)01

**Variable data:** reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

(01) 07899330095755

(17) 270920

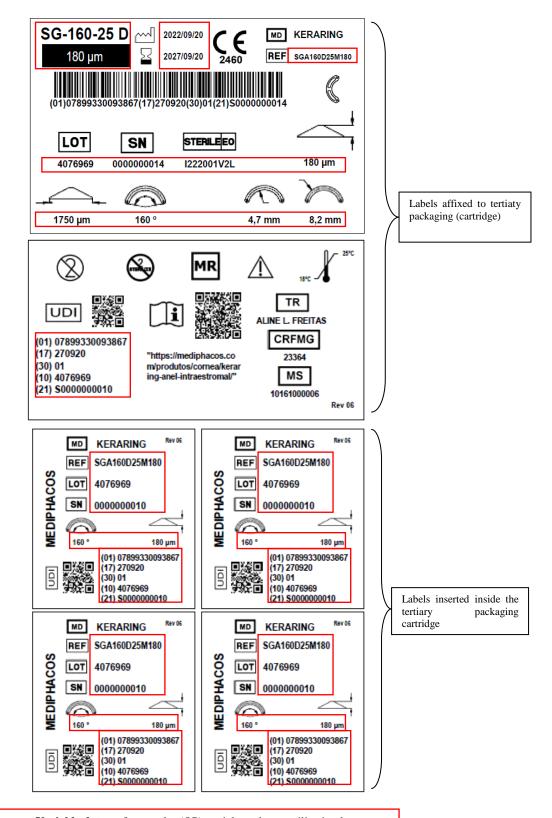
(10) 4076964

(21) S0000000005

(30) 01

EE EMB 14 - Keraring Review 09 Page 7 of 10

## c) SG Models



**Variable data:** reference, lot (OP), serial number, sterilization lot, date of manufacture, expiration date, UDI and model specifications.

EE EMB 14 - Keraring Review 09 Page 8 of 10

## Layouts:

200050003 Zebra Autofit Tag SI Rev 06 200050003 Zebra Autofit Tag AS Rev 06 200050003 Zebra Autofit Tag SG Rev 06

• **Dimensions:** 97 x 220 mm

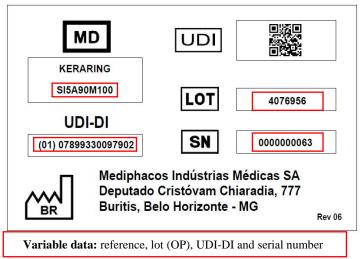
Material: resin adhesive, transthermic
Front material: 67 to 75; 71 micron
Protective material: 52 to 59; 55.5 g/m2
Total weight: 133 to 150; 141.5 g/m2
Total thickness: 132 to 150; 141 micron

Release: 6 to 14; 180° gf/1inType of printing: flexography

• Varnish: no

• **Minimum spacing:** 3mm ±1

## 4.1.5.4 Implant card label:

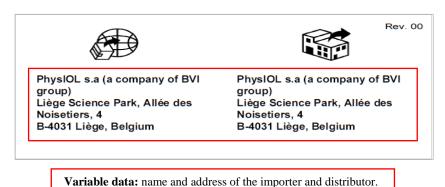


• Layout: 200050003 Sticker Zebra Autofit Implant Card Rev 06

• **Dimensions:** 9,3 x 6,0 mm

Material: resin adhesive, transthermicDisposition: affixed to the implant card.

## 4.1.5.5 Importer and distributor label



•

• Layout: 200050085 Keraring Importer and Distributor Label Rev 00

Dimensions: 80 x 40 mmMaterial: rubber couch

• **Disposition:** affixed by the European Community importer to the tertiary packaging (cartridge).

EE EMB 14 - Keraring Review 09 Page 9 of 10

**Note 1:** If there is any need to change the layout or the information on the label 200050085, the Mediphacos logistics sector, the Mediphacos importer in the European Union and the other importers to which this label applies must be communicated.

# 4.1.5.6 Shipping label

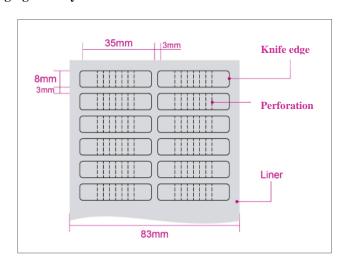


Layout: 900060042 Shipping label
Dimensions: 105 x 138 mm
Material: Coated Paper

• Adhesive: Acrylic

• **Arrangement:** Affixed to the product's transport boxes.

## 4.1.1 Primary packaging security seal



EE EMB 14 - Keraring Review 09 Page 10 of 10

• Layout: 200030059 Security Seal Labels for Cases Rev 00

• **Dimensions**: 35,0 x 8,0 mm

• Material: bopp transparent, adhesive acrylic

• **Disposition:** affixed to the cover and body of the primary package (case).

## 4.1.6 Embalagem de embarque

See current version EE EMB 17.

#### 4.1.7 Instruction for use:

- Layout: 200010006 IFU Keraring Rev 11
- **Disposition:** inserted in the tertiary package (cartridge).

#### IV. ANNEXES

Not applicable.

## V. REFERENCES

ANVISA. Resolution of the Collegiate Board - RDC N 665, of March 30, 2022.

MDR EN ISO 13485:2016\_A11:2021 - Medical devices - Quality management systems -Requirements for regulatory purposes.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

EN 15223-1:2021 - Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements.

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

EN ISO 20417 2021&LC:2021- Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12).

IPA GQA 08 - Packaging and Marketing Material Control

DET IC 14 - Keraring Case

DET IC 30 Tyvek Surgical Grade Paper Envelope EO 8x18

EE EMB 17 Shipping Boxes